

CLAIMS

1. Composition, CHARACTERIZED in that it comprises a mixture of diterpenic Labdanes obtained from a plant *Andrographis paniculata* dried extract, whose general
5 formulae are:

$C_{20}H_{30}O_5$ Andrographolide

$C_{20}H_{30}O_4$ 14-Deoxiandrographolide

$C_{26}H_{41}O_8$ Neoandrographolide

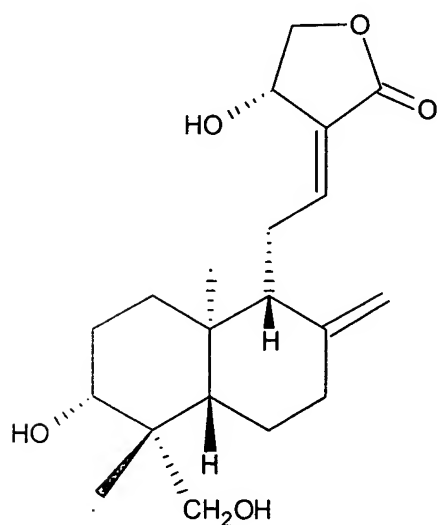
- 10 2. The composition, according to claim 1, wherein the andrographolide component is characterized by:

i.) general formula: $C_{20}H_{30}O_5$

ii.) molecular weight: 350.46

iii.) molecular nomenclature: 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,ha-
15 dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-
furanone,

iv.) molecular structure:



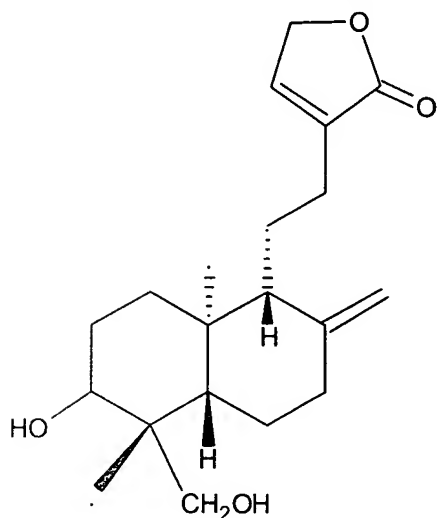
3. The composition, according to claim 1, wherein the 14-Deoxiandrographolide component is characterized by:

i.) general formula: $C_{20}H_{30}O_4$

ii.) Molecular weight: 336.46

5 iii.) Molecular nomenclature:

iv.) Molecular structure:



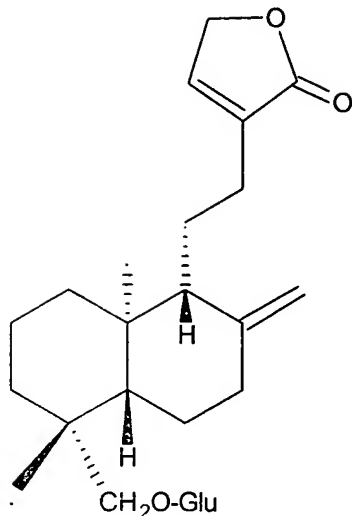
4. The composition, according to claim 1, wherein the neoandrographolide component is characterized by:

i.) general formula: $C_{26}H_{41}O_8$

ii.) molecular weight: 345.89

iii.) molecular nomenclature:

iv.) molecular structure:



5. Use of the composition, according to claim 1, CHARACTERIZED in that it is useful for preparing a medicine, drug, pharmaceutical.

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6. Use of the composition, according to claim 1, CHARACTERIZED in that it is useful for preparing a medicine suitable for treating autoimmune diseases.

7. Use of the composition, according to claim 1, CHARACTERIZED in that it is particularly useful for preparing a medicine suitable for treating rheumatoid arthritis.

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8. Use of the composition, according to claim 1, CHARACTERIZED in that it is particularly useful for preparing a medicine suitable for treating lupus exanthematous.

9. Use of the composition, according to claim 1, CHARACTERIZED in that it is particularly useful for preparing a medicine suitable for treating multiple sclerosis.

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10. Use of the composition, according to claim 1, CHARACTERIZED in that it is useful for preparing a medicine suitable for preventing and treating Alzheimer's disease.

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11. Use of the composition, according to claim 1, CHARACTERIZED in that it is particularly useful for preparing a medicine suitable for treating asthma and allergies.

5 12. Use of the composition, according to claim 1, CHARACTERIZED in that it is particularly useful for preparing a medicine suitable for treating psoriasis.

13. Use of the composition, according to claim 1, CHARACTERIZED in that, it is particularly useful for preparing a medicine suitable for treating the systemic
10 dermatomyocytis.

14. Use of the composition, according to claim 1, CHARACTERIZED in that, particularly, it is useful for preparing a medicine suitable for treating osteoarthritis.

15 15. Use of the composition, according to claim 1, CHARACTERIZED in that it is useful for preparing a medicine suitable for treating acquired immune deficiency syndrome (AIDS).

16. Use of the composition, according to claim 1, CHARACTERIZED in that it is
20 useful for preparing a medicine suitable for treating diabetes mellitus.

17. Use of the composition, according to claim 1, CHARACTERIZED in that it is useful for preparing a medicine suitable for treating the rejection in patients with tissue and organ transplants.

25 18. Pharmaceutical compositions, CHARACTERIZED in that it comprises the composition according to claim 1 and a pharmaceutically acceptable carrier.

19. The pharmaceutical composition, according to claim 18, CHARACTERIZED in that the diterpenic Labdanes mixture comprises from 20 to 40% w/w of Andrographolide, from about 3 to 6% w/w of 14-Deoxyandrographolide, and from
5 about 0.2 to 0.8% w/w of Neoandrographolide, in the final dried extract.

20. The pharmaceutical composition, according to claim 19, CHARACTERIZED in that the diterpenic Labdanes mixture comprises from about 25 to 35% w/w of Andrographolide, from about 4.5 to 5.5% w/w of 14-Deoxyandrographolide, and from
10 about 0.4 to 0.8% w/w of Neoandrographolide in the final dried extract.

21. The pharmaceutical composition, according to claim 20, CHARACTERIZED in that the diterpenic Labdanes mixture comprises 24.6% w/w of Andrographolide, 4.8% w/w of Deoxyandrographolide, and 0.6% w/w of Neoandrographolide, based in the
15 final dried extract.

22. Pharmaceutical composition, according to claims 18-21, CHARACTERIZED in that it corresponds to a pharmaceutical formulation in tablet form.

20 23. Pharmaceutical composition, according to claim 22, CHARACTERIZED in that it is orally administered contributing with the following doses for the following molecules:

- a) 1-5 mg andrographolide/kg per day
- b) 0.2 – 1 mg 14-deoxyandrographolide/kg per day
- 25 c) 0.02-0.12 mg Neoandrographolide/kg per day.

24. Use of the pharmaceutical composition, according to claims 22 and 23,
CHARACTERIZED in that it is useful for treating autoimmune diseases.

25. Use of the pharmaceutical composition, according to claims 22 and 23,
5 CHARACTERIZED in that it is useful for treating rheumatoid arthritis.

26. Use of the pharmaceutical composition, according to claims 22 and 23,
CHARACTERIZED in that it is useful for treating lupus exanthematous.

10 27. Use of the pharmaceutical composition, according to claims 22 and 23,
CHARACTERIZED in that it is useful for treating multiple sclerosis.

28. Use of the pharmaceutical composition, according to claims 22 and 23,
CHARACTERIZED in that it is useful for preventing and treating Alzheimer's
15 disease.

29. Use of the pharmaceutical composition, according to claims 22 and 23,
CHARACTERIZED in that it is useful for treating asthma and allergies.

20 30. Use of the pharmaceutical composition, according to claims 22 and 23,
CHARACTERIZED in that it is useful for treating psoriasis.

31. Use of the pharmaceutical composition, according to claims 22 and 23,
CHARACTERIZED in that it is useful for treating systemic dermatomyocytis.

25 32. Use of the pharmaceutical composition, according to claims 22 and 23,
CHARACTERIZED in that it is useful for treating osteoarthritis.

33. Use of the pharmaceutical composition, according to claims 22 and 23, CHARACTERIZED in that it is useful for treating the acquired immune deficiency syndrome (AIDS).

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34. Use of the pharmaceutical composition, according to claims 22 and 23, CHARACTERIZED in that it is useful for treating diabetes mellitus.

35. Use of the pharmaceutical composition, according to claims 22 and 23, CHARACTERIZED in that it is useful for treating rejection of organs and tissues in transplanted patients.

36. Pharmaceutical compositions, according to claim 18, CHARACTERIZED in that they can be in suitable enteral, parenteral, dermic, ocular, nasal, otic, rectal, vaginal, urethral, bucal, pharyngeal-tracheo-bronchial pharmaceutical forms, wherein the pharmaceutical composition comprises a dried extract containing a diterpenic Labdane mixture of andrographolide, 14-deoxyandrographolide and Neoandrographolide.

37. The pharmaceutical compositions, according to claim 36, CHARACTERIZED in that the diterpenic Labdane mixture comprises from 20 to 40% w/w of Andrographolide, from about 3 to 6% w/w of 14-Deoxyandrographolide, and from about 0.2 to 0.8% w/w of Neoandrographolide, based in the final dried extract weight.

38. The pharmaceutical compositions, according to claim 37, CHARACTERIZED in that the diterpenic Labdane mixture comprises from about 25 to 35% w/w of

Andrographolide, from about 4.5 to 5.5% w/w of 14-Deoxyandrographolide, and from about 0.4 to 0.8% w/w of Neoandrographolide based in the final dried extract weight.

39. The pharmaceutical compositions, according to claim 38, CHARACTERIZED in that the diterpenic Labdane mixture comprises 24.6% w/w of Andrographolide, 4.8% w/w of Deoxyandrographolide, and 0.6% w/w of Neoandrographolide, based in the final dried extract weight.

40. Pharmaceutical compositions, according to claim 36, CHARACTERIZED in that they are administered by the corresponding routes, in the following doses:

- a) 1-5 mg andrographolide/kg per day
- b) 0.2 – 1 mg of 14-deoxyandrographolide/kg per day
- c) 0.02 – 0.12 mg Neoandrographolide/kg per day.

41. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating autoimmune diseases.

42. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating rheumatoid arthritis.

43. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating lupus exanthematous.

44. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating multiple sclerosis.

45. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for preventing and treating Alzheimer's disease.

5 46. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating asthma and allergies.

47. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating psoriasis.

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48. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating systemic dermatomyocytis.

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49. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating osteoarthritis.

50. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating acquired immune deficiency syndrome (AIDS).

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51. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating diabetes mellitus.

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52. Use of the pharmaceutical composition, according to claims 36 to 40, CHARACTERIZED in that it is useful for treating the rejection of organs and tissues in transplanted patients.